

Thomas S. Szatkowski  
Wyeth  
Five Giralda Farms  
Madison, NJ 07940In Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,563,146**MAILED****JAN 22 2007**

CENTRAL REEXAMINATION UNIT

**NOTICE OF FINAL DETERMINATION**

A determination has been made that U.S. Patent No. 5,563,146, which claims a method of treatment using the approved medical device CYPHER®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 557 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 557 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of February 3, 2006, (71 Fed. Reg. 5860). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (513) + 301 \\ &= 577 \text{ days (1.5 years)}\end{aligned}$$

Since the regulatory review period began February 1, 2001, after the patent issued (October 8, 1996), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,563,146
Granted:	October 8, 1996
Original Expiration Date <sup>1</sup> :	April 28, 2012 <sup>2</sup>
Applicant:	Randall E. Morris et al.
Owner of Record:	Wyeth
Title:	METHOD OF TREATING HYPER-

<sup>1</sup>Subject to the provisions of 35 U.S.C. § 41(b).

<sup>2</sup>Based on Terminal Disclaimer filed over U.S. Patent No. 5,188,711.

PROLIFERATIVE VASCULAR DISEASE

Product Trade Name: CYPHER®

Term Extended: 557 days

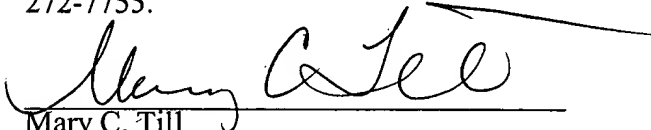
Expiration Date of Extension: November 6, 2013

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



Mary C. Till  
Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Office of Regulatory Policy  
HFD - 7  
5600 Fishers Lane (Rockwall II Rm. 1101)  
Rockville, MD 20857

Attention: Beverly Friedman

RE: CYPHER®  
FDA Docket No.: 2003E-0407